REMARKS

The Office action dated March 21, 2008, is acknowledged. Claims 1-37 are pending in the instant application. According to the Office action, claims 1-15 and 23-31 has been rejected. Claims 16-22 and 32-37 have been objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The Applicants thank the Examiner for this conclusion. By the present Office Action response, claims 1, 9, 16, 18, 19 and 23 have been amended, claim 24 has been canceled and claims 38-47 have been added. In particular, step (d), such as in claim 16, has been amended to clarify that the step includes dripping a partial amount of the solution onto a carrier material, support for which may be found throughout the present specification, such as at paragraph [000034]. Claims 18 and 19 have been amended as independent claims which include the additional limitations of claim 9. Claim 23 has been amended to depend from claim 9 rather than claim 19. Claim 1 has been amended to recite the claim in the form of a product-by-process claim, including the steps of claim 16 and to include the additional limitation of "or removing oxygen from a solvent or solvent mixture by using a light-impermeable vessel," support for which may be found in the original specification at page 10, step A. Claim 9 has been amended to depend from claim 1 and to pertain to an adhesive wound dressing. New claims 38-41 have been added and recite wound dressings having a low peroxide content, in particular a carrier material having a peroxide content not exceeding the value 10 (support for which may be found in claims 7, 22, 27, 35-37). Reconsideration is respectfully requested in light of

the amendments being made hereby and the arguments made herein. No new matter has been added.

Rejection of claims 1-6 and 23-26 under 35 U.S.C. 102(b)

Claims 1-6 and 23-26 have been rejected under 35 U.S.C. 102(b) as being anticipated by EP Patent No. 0 338 173 (Yamazaki, et al.). The Examiner essentially concludes that Yamazaki, et al. disclose every limitation recited in present claims 1-6 and 23-26 as explained in detail at pages 2-4 (Section 2) of the present Office action.

The Applicants respectfully disagree with the Examiner's conclusion and submit that the present invention as defined in the presently amended claims is patentably distinct from the invention disclosed in Yamazaki, et al. In particular, the Applicants submit that the product claims have been amended to recite wound dressings that are obtained by the specific process steps generally defined in claim 16, as said steps were considered to contain allowable subject matter per the Examiner's conclusion (Section 14, page 14 of the present Office action).

In particular, the Applicants submit that the prior art fail to disclose a manufacturing method which includes step (a) set forth in present 16 and 18 and which is now included in present claim 1, as amended. In view of step (a) being omitted in the prior art manufacturing methods, it is submitted that the wound dressings obtainable by the prior art methods are in turn different from the wound dressing obtainable by the methods according to the present invention. The presently claimed wound dressings contain adrenaline which is very unstable and which quickly disintegrates upon exposure to oxygen (paragraph [00005] of the published application). The process according to the present invention avoids this particular disadvantage (paragraph [00006] of the published

application). Due to the specific measures taken in accordance to the manufacturing process of the present invention, oxidative degradation of adrenaline is avoided and, therefore, the generation of potentially harmful degradation products is minimized, and the content of active substance (i.e., adrenaline) remains essentially constant during manufacture and subsequent storage. The presence or absence of degradation can be easily monitored since the main degradation product, adrenochrome, is of intense red color (paragraph [00005] of the published application).

It is further submitted that while Yamazaki, et al. also considers the use of epinephrine as an active agent in a wound dressing, the reference fails to teach any measures for avoiding the instability of this compound. Therefore, the prior art wound dressings will suffer from the disadvantages described in paragraph [00005] of the present application as published. In view of the above, it is submitted that the presently claimed invention is not anticipated by the cited prior art.

Regarding claim 23, it is submitted that the claim refers to the wound dressings of claims 1 and 9 which are no longer anticipated by the prior art in view of the present claim amendments. In turn, it is submitted that the rejection to claim 23 is no longer germane and should be withdrawn.

In view of the above, Yamazaki, et al. fail to teach each and every limitation of the present claims as amended and therefore fail to anticipate the present invention. Withdrawal of the present rejection is respectfully requested.

Rejection of claims 7-15 and 27-31 under 35 U.S.C. 103(a)

Claim 27 has been rejected as being unpatentable over Yamazaki, et al. in view of U.S. Publication No. 2006/0142684 (Shanbrom). The Examiner argues that Yamazaki, et

al. teach the limitations of claim 27, except for wherein the carrier material has a low peroxide content not exceeding the value 10. The Examiner refers to Shanbrom for teaching an apparatus with a sponge containing more than one percent by weight hydrogen peroxide. The Examiner concludes that it would have been obvious to modify the ionic dressing for topical administration of drugs to wounds and burns of Yamazaki, et al. with a carrier material having a low peroxide content not exceeding the value 10 in order to arrive at the invention of present claim 27. The remaining obviousness rejections are set forth in detail at pages 11-13 (Sections 11-13) of the present Office action.

The Applicants respectfully submit that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitation. The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider the teachings of the cited prior art alone, or in combination, each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered. In addition, prior art must be considered in its entirety, i.e., as a whole (emphasis provided), including portions that would lead away from the claimed invention (M.P.E.P. §2141.02, citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220, USPQ 303 (Fed. Cir. 1983), *cert.*

denied, 469 U.S. 851 (1984)), proposed modification cannot render the prior art unsatisfactory for its intended purpose or change the principle of operation of a reference (M.P.E.P. §2143.01), and Examiner's conclusion of obviousness may not be based on improper hindsight (M.P.E.P. §2145(X)(A)).

The Applicants first submit that the aforementioned claims have been amended as independent claims to take into account the allowable subject matter, as noted by the Examiner in Section 14 of the Office action. In view of this, it is submitted that the claims are allowable and the present obviousness rejections should be withdrawn.

The Applicants also submit that regarding claim 1 (and any claims depending therefrom), none of the cited prior art specifically relate to adrenaline (epinephrine) and none of the cited prior art teach any methods that are particularly suitable for manufacturing wound dressings containing this particular active substance. As noted above, the Examiner has acknowledged that the subject matter of claim 16 is allowable subject matter. Since the products obtained by the processes according to the present invention are different from the prior art wound dressings due to the aforementioned reasons discussed at length above, it is respectfully submitted that the subject matter of claim 1 (as amended) is likewise non-obvious in view of the cited prior art.

Regarding new claims 38-41, in particular the limitation relating to a "low peroxide content" or a "peroxide content not exceeding the value 10," the Examiner has referred to Shanbrom for teaching an apparatus with a sponge containing more than one percent by weight hydrogen peroxide. However, it is submitted that Shanbrom teaches away from the present invention and the proposed combination of the teachings of Shanbrom with those of Yamazaki, et al. does not arrive at the presently claimed

invention, as will be explained below.

In particular, Shanbrom relates to an oxygen-releasing bandage in which hydrogen peroxide is stored as a complex formed with a polymer (acetal plastic). Upon being placed on a wound, the oxygen is released from the complex due to the action of enzymes which are present in the wound fluid (with reference to the Abstract of the document). The release of oxygen is considered to result in improved wound disinfection. However, the Applicants submit that it is well known in the art that the oxygen produced from hydrogen peroxide is very aggressive as it is present "in statu nascendi." Due to these properties, this chemical reaction is often employed for bleaching or disinfection (e.g., disinfection of wounds as described by Shanbrom). Disinfection results from oxidative degradation of viruses, bacteria, etc.

The Applicants further submit that it would also be known to one skilled in the art that an oxygen-releasing bandage as described by Shanbrom must never be combined with medicinal active substances, as the nascent oxygen would rapidly oxidize and therefore inactivate the medicinal active substances. In accordance with this known situation, Shanbrom fails to teach the possibility of additionally including any medicinal active substances into the oxygen releasing bandage as this would be technically illogical. Therefore, the Applicants respectfully disagree with the Examiner's rationale on page 6, first paragraph of the Office action for combining the teachings of Yamazaki, et al. with those of Shanbrom. In particular, it is respectfully submitted that one skilled in the art would have never considered the possibility of modifying the drug-containing wound dressings disclosed by Yamazaki, et al. by incorporating an oxygen-producing substance as taught by Shanbrom since the nascent oxygen would readily destroy and inactivate the

drug contained in the wound dressing. This clearly would be an undesirable result and would render the resultant product unusable.

More particularly, the oxygen-producing substance taught by Shanbrom would be absolutely incompatible for combined use with adrenaline which rapidly decomposes in the presence of oxygen (see, for example, paragraph [00005] of the present specification). Therefore, the teachings of Shanbrom are incommensurate with the present invention as well as with the teachings of Yamazaki, et al. The teachings of Yamazaki, et al. and Shanbrom are in conflict and therefore cannot be combined to support the present obviousness rejections. Moreover, Shanbrom teaches away from the present invention since it teaches that the hydrogen peroxide content should be maximized in order to produce high amounts of oxygen (page 2, [0021]). This is in conflict with the present invention which requires the oxygen content or peroxide content be reduced to very low levels, e.g., by the process of step (a) of claim 16 or by selected carrier materials having a low content of peroxides (present claims 38-41).

It is therefore respectfully submitted that the present invention defined in the presently amended claims is patentably distinguishable over the combination of prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the present invention recited in the instant claims are not taught or disclosed in the prior art references, alone or in combination. Moreover, one skilled in the art would not be motivated to combine the teachings of said references or to modify the cited prior art references to arrive at the presently claimed invention, and the cited prior art references teach away from the present invention. Therefore, the Applicants respectfully request that these obviousness rejections be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicants strongly urge that the obviousness-type rejection and anticipation rejections be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

Date: July 18, 2008

By: _____
D. Peter Hochberg
Reg. No. 24,603

D. Peter Hochberg Co., L.P.A.
1940 East 6th Street, 6th Floor
Cleveland, OH 44114
(216) 771-3800